REMARKS

The above amendment and the following remarks are submitted in response to the Office Action of September 11, 2006. Claims 40-64 are pending, with Claims 48-50 and 59-61 withdrawn, and the remaining claims standing rejected. The above amendment cancels Claims 41, 52 and 62-64. Reconsideration is respectfully requested.

Objection to Claims

Claim 40 was objected to because of the use of "pain/inflammation and/or spasm", which has been deleted in the above amendment. The term "pain/inflammation inhibitory agents" has been maintained, given that pain and inflammation mechanisms are closely linked and the usage of this term throughout the specification, rendering its meaning clear.

Claims 40 and 51 were objected to due to what were perceived to be improper "wherein" clauses. The claims have been amended to insert "wherein" as suggested by the Examiner, without narrowing of scope, to expedite prosecution of the application.

Rejection of Claims Under 35 USC § 112, First Paragraph

As best understood by the undersigned attorney, the claims were rejected under 35 USC § 112, First Paragraph because, while enabled for the "reduction" of restenosis or spasm and for classes of agents, the claims were not viewed as enabled for the "preemptive inhibition" of restenosis or spasm when "inhibition" is defined as "prevention, completely cure or eradication" of such an effect. Applicants respectfully traverse this rejection. Claim terms are interpreted first in view of the meaning that they are given in the specification, and a dictionary definition (as was cited in the Office Action) does not trump the definition from the specification. *C.R. Bard Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). In the instant case, "inhibitory" agents are clearly defined as agents that "limit" rather than completely cure or eradicate restenosis, pain, inflammation or spasm. *See, e.g.*, specification at page 5, line 31; page

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6, line 25. When properly interpreted in view of the specification, the claims are not directed to the eradication of inhibition, and it is submitted that this rejection should be withdrawn.

The claims were also rejected due to claiming a broad variety of possible anti-restenosis and anti-spasm agents. Applicants respectfully traverse this rejection. The Office Action cites two papers as suggesting that particular agents are not effective. One of these (Tanajura) is for systemically delivered diltiazem, rather than locally delivered agents as claimed. The other reference (Tollefson) concerns the monitoring of heparin cofactor II in plasma levels, rather than the administration of therapeutics. The instant specification is full of support from the literature for the anti-restenotic, anti-spasm or anti-inflammatory effects of the individual claimed agents. Individually, these agents are well known and characterized. The present invention lies in their combination and local delivery of such combinations to a vascular site. Applicants further submit that routine assays are known to those of skill in the art that can be used should there be a question as to whether a given agent is within the scope of the invention, which assays are cited in the literature referenced throughout the specification.

Rejection of Claims Under 35 USC § 112, Second Paragraph

The Office Action found several claim terms to be indefinite. In response to this rejection, Applicants have amended independent Claims 40 and 51 to eliminate "use" language, eliminate reference to "preemptive inhibition" and "selectivity", to put in a precise concentration range, and to eliminate "including" within the Markush groups listing classes of agents. The term "differing molecular targets" was retained, as this term is clearly defined as meaning that the plurality of agents act on different receptors enzymes or ion channels within the specification. *See, e.g.*, page 14, line 1 – page 15, line 22. Applicants submit that this rejection has been overcome.

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Rejection of Claims Under 35 USC § 101

The claims were rejected as being in improper form due to being directed to a use without steps. Claims 40 and 51 have been amended to be clearly directed to compositions, thus overcoming this rejection.

Rejection of Claims Under 35 USC § 103

The claims were rejected as being obvious over the hypothetical combination of US 5,786,362 to Krongrad in view of US 4,906,646 to Honn. Applicants respectfully traverse this rejection. The present compositions are formulated for local delivery to a vascular operative site during an operative procedure. Claims 40 and 51 have been amended above to reflect that the claimed combinations of agents are included within a liquid carrier adapted for perioperative delivery to an operative vascular site, with each claimed agent being included at a concentration of no greater than 100,000 nanomolar.

Krongrad is directed to methods of treating hormone independent cancer, rather than undesirable processes following a vascular procedure. Inhibitors of protein kinase C are delivered to inhibit or kill cells of late stage hormone dependent cancers. (Column 1, lines 46-51). Delivery methods are not disclosed. There is a complete absence of disclosure of local delivery, or the use of a carrier suitable for local delivery, or suitable for perioperative vascular delivery.

Honn is also directed to methods and compositions for treating tumors, using a composition including a platinum coordination compound and a dihydropyridine calcium channel blocker. The composition is delivered orally or parenterally (column 8, lines 7-23). The compounds are administered over a period of several days (abstract). Honn does not disclose a locally delivered formulation as claimed.

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Neither Krongrad or Honn is concerned with inhibiting restenosis or locally delivered compositions. A hypothetical combination of the Krongrad and Honn compositions would be in an oral or parenteral form, and would include a platinum coordination compound per Honn, with uncertain result on vasculature. In short, a combination of Krongrad and Honn falls short of the claimed invention.

Conclusion

In view of the above, reexamination and passage to issue of Claims 40, 42-51 and 53-61 is requested. The Examiner is invited to telephone the undersigned attorney to discuss this application should there be any questions.

Respectfully Submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid and addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

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